1641 IFW

PATENT

Case Docket No. RLUTHER.013A
Date: July 19, 2004

In re application of	:	Ronald B. Luther, et al.
Appl. No.	:	10/003,782
Filed	:	October 31, 2001
For	:	UNIVERSAL PASSIVE PROTECTOR FOR AN IV CATHETER
Examiner	:	Ann Y. Lam
Art Unit	:	1641

I hereby certify that this correspondence and all marked attachments are being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Mail Stop Appeal Brief - Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on

July 19, 2004
(Date)

Steven J. Nataupsky, Reg. No. 37,668

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith in triplicate is an Appellants' Brief to the Board of Patent Appeals:

(X) Fee for filing brief in the amount of $165 is enclosed.

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Time Extension Fee: (X) one month ($55)

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(X) If applicant has not requested a sufficient extension of time and/or has not paid any other fee in a sufficient amount to prevent the abandonment of this application, please consider this as a Request for an Extension for the required time period and/or authorization to charge our Deposit Account No. 11-1410 for any fee which may be due. Please credit any overpayment to Deposit Account No. 11-1410.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Ronald B. Luther, et al.	Group Art Unit: 1641
Appl. No.	:	10/003,782	
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Steven J. Natalpsky, Reg. No. 37,668

APPELLANTS' BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Appellants hereby appeal to the Board of Patent Appeals and Interferences the final rejection in the above-captioned patent application set forth in an Office Action mailed on November 18, 2003.

REAL PARTY IN INTEREST

The real party in interest in this appeal is the assignee of this application, Luther Research Partners, LLC.

RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

STATUS OF THE CLAIMS

Claims 1-20 are pending in the application. Claims 1, 2, 4-9, 11, 12, 14-18 and 20 stand rejected in the Final Office Action mailed on November 18, 2003. The Examiner objects to the remaining claims. Appellants hereby appeal Claims 1, 2, 4-9, 11, 12, 14-18 and 20.

STATUS OF AMENDMENTS

No Amendment has been filed subsequent to the Final Office Action of November 18, 2003. Therefore, the claims before the Board appear as they were finally rejected.

APPELLANTS' INVENTION

Medical professionals commonly use intravenous needles to insert and withdraw fluid from patients. However, when introducing or withdrawing large amounts of fluid, the intravenous device is disposed within a blood vessel of a patient for an extended period of time. Metal needles are disadvantageous for such uses, because their rigid structure and sharp distal tip can cause trauma to the patient's vessel. Thus, medical professionals commonly use a catheter for such applications.

A catheter typically comprises a flexible tube having a soft tip. Catheters are generally inserted into the patient's vessel using a catheter introduction device. One type of introduction device comprises an over-the-needle catheter system. In such over-the-needle catheter systems, a thin, hollow catheter having a hub attached to its proximal end is disposed over a rigid cannula, such as a needle. The cannula and catheter are simultaneously inserted into a desired vessel. After insertion, the cannula is withdrawn from within the catheter interior. The distal end of the catheter remains disposed within the patient's vessel. Thereafter, a hub mounted to the proximal end of the catheter may be used to fluidly connect the catheter to an infusion line or device.

Immediately after the cannula is withdrawn from the catheter, the piercing cannula tip is generally exposed. As long as the cannula tip remains exposed, both the patient and the attendant medical personnel are susceptible to being accidentally stuck by the sharp tip. In recent years, concern over such accidental needlesticks has become more pronounced because of the advent of currently incurable and fatal diseases, such as Acquired Immune Deficiency Syndrome ("AIDS") and hepatitis. AIDS can be transmitted by the exchange of bodily fluids from an infected person to another person. A needle that has been used to place a catheter in the vein of an AIDS infected person is a vehicle for transmission of the disease. Thus, it is advantageous to cover or protect a needle immediately after use to avoid needlesticks or other contact.

Appellants' application provides a universal passive protector for an IV catheter. (Spec. page 1, lines 6 and 7). In a preferred embodiment, Appellants' protector comprises an over-the-

needle catheter including a hub. (Spec. page 6, lines 27 and 28). A hub trap comprising first and second arms retains the hub. (Spec. page 6, lines 28 and 29). The first and second arms grip the hub from the outside, such that the hub is located between the arms. (Spec. page 11, lines 14-24; Figures 1A-1D, 2B, 2C, 3, 5A, 5B, 6 and 7). Radial protrusions on the hub prevent the hub from escaping the arms. (Spec. page 11, lines 14-24; Figures 1A-1D, 2B, 2C, 3, 5A, 5B, 6 and 7). The present protector is thus universal, because all standard catheter hubs include radial protrusions, or a lip.

A slider connected to a proximal end of the needle is movable along a sheath from a distal position to a proximal position. (Spec. page 6, lines 29 and 30). When the slider is in the distal position, the needle extends through the hub trap. (Spec. page 6, line 30 through page 7, line 1). The needle retains the first and second arms in a closed position wherein the catheter hub is trapped between the first and second arms. (Spec. page 7, lines 1 and 2).

When the slider is in the proximal position, a distal tip of the needle is proximal of the locking structure. (Spec. page 7, lines 2 and 3). The needle thus no longer retains the first and second arms in the closed position, and the arms move into an open position, thereby releasing the catheter hub from the hub trap. (Spec. page 7, lines 3 and 4). When the arms are in the open position, interlocking fingers of the first and second arms block the needle from reemerging from the sheath. (Spec. page 7, lines 5 and 6). The present protector thus ensures that the sharp needle tip is safely stowed before the hub trap releases the catheter hub (Spec. page 7, lines 6 and 7), preventing the risk of transferring diseases to healthcare workers.

The present protector for an IV catheter is described in full detail in the portion of the specification entitled "Detailed Description of the Preferred Embodiments," at pages 8-16 of the specification.

ISSUES BEFORE THE BOARD

The first issue before the Board is whether the subject matter of Claims 1, 2, 4-9, 11, 12, 14-18 and 20 is anticipated under 35 U.S.C. § 102(b) by U.S. Patent No. 5,599,310 to Bogert.

The second issue before the Board is whether the subject matter of Claims 1, 2, 9 and 11 is anticipated under 35 U.S.C. § 102(e) by U.S. Patent No. 6,520,938 to Funderburk et al. (hereinafter "Funderburk").

The third and final issue before the Board is whether the subject matter of Claim 8 is obvious under 35 U.S.C. § 103(a) over Funderburk.

GROUPING OF THE CLAIMS

As set forth in the first through third issues before the Board, each group of claims under each issue stands rejected under a different reference. Therefore, each of these groups of claims is patentable for separate reasons.

With regard to the first issue before the Board, Claims 1, 2, 4-9, 11, 12, 14-18 and 20 do not stand or fall together. Rather, Claims 1, 2 and 5-8 stand or fall together, Claim 4 stands or falls separately, Claim 9 stands or falls separately, Claim 11 stands or falls separately, Claims 12 and 15-17 stand or fall together, Claim 14 stands or falls separately, Claim 18 stands or falls separately, and Claim 20 stands or falls separately.

With regard to the second issue before the Board, Claims 1, 2, 9 and 11 do not stand or fall together. Rather, Claims 1 and 9 stand or fall together, Claim 2 stands or falls separately, and Claim 11 stands or falls separately.

With regard to the third and final issue before the Board, Claim 8 stands or falls on its own merit.

APPELLANTS' ARGUMENTS

Rejections under 35 U.S.C. § 102(b) (Issue Number 1)

The Examiner has rejected Claims 1, 2, 4-9, 11, 12, 14-18 and 20 under 35 U.S.C. § 102(b) as being anticipated by Bogert. However, Bogert neither discloses nor suggests Appellants' claimed universal passive protector for an IV catheter.

Appellants' Claims 1 and 12 each recite at least a universal passive protector for an IV catheter. Accordingly, Appellants' protector is capable of functioning with any standard catheter hub. With reference to Figure 1D, Appellants' application discloses a typical catheter hub 24. The hub includes first and second opposite radial protrusions 48. (Spec. page 9, lines 25 and 26). All standard catheter hubs include similar protrusions or a lip. The protrusions or lip enable the hub to engage a standard luer lock. (Spec. page 9, line 28). Advantageously, the protrusions also enable Appellants' hub trap 32 to securely hold the hub 24. (Figures 2B, 2C and 3; Spec. page 9, line 27 and page 11, lines 18-24).

Because Appellants' protector is configured to engage the protrusions on any standard catheter hub, Appellants' protector is universal. By contrast, the distal ends of the fingers 34 of Bogert include detents 46. (*See* Figure 3 of Bogert). The detents 46 are configured to engage corresponding recesses 50 in the catheter hub 14. (col. 3, lines 64-67). These recesses 50, however, are specially formed in the catheter hub 14 so as to make the hub 14 compatible with the catheter assembly 10 of Bogert. Standard catheter hubs do not include any such recesses. Accordingly, the catheter assembly 10 of Bogert is not universal, because the fingers 34 of Bogert are not configured to be compatible with standard catheter hubs.

For the reasons presented above, Bogert does not disclose or suggest a universal passive protector for an IV catheter, as recited in Appellants' Claims 1 and 12. Therefore, for at least this reason, Claims 1 and 12 are allowable over Bogert. Claims 2, 4-9 and 11, which depend from Claim 1, and Claims 14-18 and 20, which depend from Claim 12, are also allowable over Bogert.

Appellants' Claims 1 and 12 further recite at least an elongate sheath. According to established rules of patent examination procedure, the term sheath must be interpreted according to its broadest reasonable interpretation. (M.P.E.P. § 2111). Furthermore, Apparatus in the prior art that does not fit within this broadest reasonable interpretation of the term sheath cannot anticipate Appellants' sheath.

The broadest reasonable interpretation for sheath is an apparatus that is adapted to cover an object. The dictionary definition of sheath supports this interpretation. For example, Merriam Webster Online provides the following definitions for sheath: 1: a case for a blade (as of a knife); ... 3: any of various covering or supporting structures that are applied like or resemble in appearance or function the sheath of a blade. (http://www.m-w.com/home.htm).

In their application, Appellants' use of the term sheath is consistent with the broadest reasonable interpretation. With reference to Figures 1A, 1B, 4A, 4B and 5B, Appellants' application discloses a variety of sheaths 34, 106. Each of the sheaths, however, have at least one characteristic in common. Each comprises a space to receive the needle 40 as the slider 38 moves from the distal position to the proximal position. (Spec. page 9, lines 17 and 18, and page 15, lines 4-18). The sheath provides a barrier around the needle. (Spec. page 15, lines 9-11). Thus Appellants' sheath comprises apparatus that is adapted to cover an object.

The sheath advantageously provides a barrier around the needle. (Spec. page 15, lines 9-11). The needle may have bodily fluids thereon, and these bodily fluids may contain

communicable diseases. The sheath prevents these fluids from contacting any person in the vicinity of the needle, such as a technician or a patient. (Spec. page 15, lines 9-11). The sheath also prevents these fluids from contacting any surface outside the sheath. The sheath thus prevents bodily fluids from being deposited on a given surface, so that people who later contact that surface are not exposed to the bodily fluids.

By contrast, the cannula guard 30 of Bogert does not cover or surround the cannula 16. (Figure 23). In fact, Bogert teaches that it is preferable for the cannula guard to reside around less than half the circumference of the cannula. (col. 5, lines 58-62). Thus, the needle of Bogert can easily transfer diseases, such as AIDS, to healthcare workers. The Bogert device is not safe and does not include the sheath set forth in the present claims. Accordingly, the cannula guard 30 of Bogert does not anticipate or render obvious Appellants' protector.

For the reasons presented above, Bogert does not disclose or suggest an elongate sheath, as recited in Appellants' Claims 1 and 12. Therefore, Claims 1 and 12 are allowable over Bogert. Claims 2, 4-9 and 11, which depend from Claim 1, and Claims 14-18 and 20, which depend from Claim 12, are also allowable over Bogert.

Appellants' Claims 1 and 12 further recite at least that a hub is trapped between first and second arms. By contrast, the fingers 34 of Bogert grip the catheter hub 14 from the inside of the hub 14. (Figures 1 and 2A). The hub 14 thus is not between the fingers 34. Accordingly, the configuration of Bogert's hub 14 and fingers 34 does not anticipate or render obvious Appellants' claimed hub trap.

The relative positioning of Appellants' hub and arms contributes to the universal nature of Appellants' protector. As described above at pages 2-5, Appellants' protector is advantageously capable of functioning with any standard catheter hub. The positioning of the hub between Appellants' arms enables the arms to interact with the tabs, lip, or radial protrusions, that are present on every standard catheter hub.

For the reasons presented above, Bogert does not disclose or suggest a universal device, a sheath, or a hub located between first and second arms, as recited in Appellants' Claims 1 and 12. Therefore, Claims 1 and 12 are allowable over Bogert. Claims 2, 4-9 and 11, which depend from Claim 1, and Claims 14-18 and 20, which depend from Claim 12, are also allowable over Bogert.

Rejections under 35 U.S.C. § 102(e) (Issue Number 2)

The Examiner has rejected Claims 1, 2, 9 and 11 under 35 U.S.C. § 102(e) as being anticipated by Funderburk. However, Funderburk neither discloses nor suggests Appellants' claimed universal passive protector for an IV catheter.

Appellants' Claim 1 recites at least a universal passive protector for an IV catheter. Accordingly, and as described in detail above with respect to Bogert, Appellants' protector is capable of functioning with any standard catheter hub. Because Appellants' protector is configured to be compatible with any standard catheter hub, Appellants' protector is universal.

By contrast, the cannula housing 14 of Funderburk includes open latch ports 58 formed in the proximal face 42 of the cannula housing 14. The latch ports 58 include undercut recesses 60 that engage latch fingers 56 on the insertion hub 16 to secure the cannula housing 14 to the insertion hub 16. (col. 5, lines 37-43; Figures 2, 3, 4 and 6). Standard cannula hubs do not include any such open latch ports 58 or undercut recesses 60. Therefore, standard cannula hubs do not include any apparatus to engage the latch fingers 56 on the insertion hub 16. Furthemore, standard cannula hubs are round, whereas the cannula housing 14 and the insertion hub 16 of Funderburk are both flat. The insertion hub 16 of Funderburk, with its flat shape and protruding latch fingers 56 could not engage a standard cannula hub. Accordingly, the medication infusion set of Funderburk is not universal.

For the reasons presented above, Funderburk does not disclose or suggest a universal passive protector for an IV catheter, as recited in Appellants' Claim 1. Therefore, for at least this reason, Claim 1 is allowable over Funderburk. Claims 2, 4-9 and 11, which depend from Claim 1, are also allowable over Funderburk.

Appellants' Claim 1 further recites at least a slider connected to a proximal end of a needle, the slider being movable along a sheath from a distal position to a proximal position. The Examiner has identified the needle guide 34 of Funderburk as a sheath, and the inserter hub 16 of Funderburk as a slider. Appellants respectfully disagree that these components of Funderburk could be considered to correspond to the apparatus described in the present application.

Appellants' sheath 34 provides a track along which Appellants' slider 38 is movable between a distal position and a proximal position. Because Appellants' slider is connected to a proximal end of the needle, movement of the slider along the sheath induces movement of the needle. As the slider moves from the distal position to the proximal position, it draws the needle into the sheath. When the slider reaches the proximal position, the needle is disposed within the sheath. The sheath protects patients and operators of Applicants' device from accidental needle sticks.

By contrast, the needle guide 34 of Funderburk is press-fit mounted within the cannula 12 (col. 4, lns. 58-62). The insertion needle 18 extends from the inserter hub 16, through the needle guide 34 and through the cannula 12 (Figure 6). The inserter hub 16 is thus not movable along the needle guide 34, as Appellants' slider is movable along Appellants' sheath. In fact, the configuration of Funderburk's device prevents the inserter hub 16 from ever even coming into contact with the needle guide 34.

Appellants' Claim 1 further recites that when the slider is in the distal position, the hub is trapped between the first and second arms, and when the slider is in the proximal position, the hub is released from the hub trap. The apparatus of Funderburk does not meet these additional claim limitations. Again, the inserter hub 16 is not movable along the needle guide 34. Thus, there is no way to identify what a configuration might look like in which the inserter hub 16 is in a distal position relative to the needle guide 34. Nor is there a way to identify what a configuration might look like in which the inserter hub 16 is in a proximal position relative to the needle guide 34.

For the sake of argument, however, one might assume that Figure 2 of Funderburk illustrates the distal position (since the needle guide 34 is located farther away from the inserter hub 16), and Figure 6 illustrates the proximal position (since the needle guide 34 is located closer to the inserter hub 16). In Figure 2, the hub 14 is not trapped between first and second arms. In fact, the hub 14 is completely released and free from the latch fingers 56. And in Figure 6, the hub 14 is not released from the hub trap. In fact, the latch fingers 56 securely hold the hub 14.

For the reasons presented above, Funderburk does not disclose or suggest a sheath or a slider, as recited in Appellants' Claim 1. Therefore, Claim 1 is allowable over Funderburk. Claims 2, 4-9 and 11, which depend from Claim 1, are also allowable over Funderburk.

Rejection under 35 U.S.C. § 103(a) (Issue Number 3)

The Examiner has rejected Claim 8 under 35 U.S.C. § 103(a) as being unpatentable over Funderburk. Claim 8 is dependent upon Claim 7, which is dependent upon Claim 1. Appellants respectfully assert that Claim 1 is allowable over Funderburk, as explained above. Therefore, Claim 8, which includes all of the limitations of Claim 1, is also allowable over Funderburk.

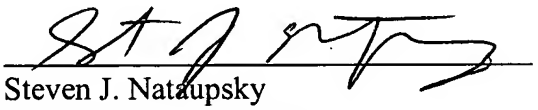
CONCLUSION

In view of the foregoing, Appellants respectfully submit that the Examiner's rejections under 35 U.S.C. § 102(b), § 102(e) and § 103(a) are not well founded. Appellants therefore respectfully request that the Board reverse the Examiner's rejections.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: July 19, 2004

By: 

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